DEPARTMENT OF HEALTH AND HUMAN SERVICE

9 14 25 d

Food and Drug Administration
New Orleans District
Southeast Region
6600 Plaza Drive, Suite 400
New Orleans, Louisiana 70127

Telephone: 504-253-4519
Facsimile: 504-253-4520

June 28, 2001

WARNING LETTER NO. 2001-NOL-30

FEDERAL EXPRESS
OVERNIGHT DELIVERY

Mr. Carl J. Dugas, Owner
Carl's Seafood
3838 B Catahoula Hwy.
St. Martinville, Louisiana 70582

Dear Mr. Dugas:

We inspected your firm, located at 3838 B Catahoula Highway, St. Martinville, Louisiana, on May 21, 2001, and found that you have serious deviations from the Seafood HACCP regulations, Title 21, *Code of Federal Regulations*, Part 123 (21 CFR 123). These deviations, some of which were previously brought to your attention, cause your vacuum packed crawfish tail meat to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find this Act and the seafood HACCP regulations through links in FDA's home page at www.fda.gov.

The following deviations were as documented:

- You must have a written HACCP plan to control any food safety hazards that are reasonably likely to occur to comply with 21 CFR 123.6(b). However, your firm does not have a HACCP plan for vacuum packed cooked crawfish tail meat to control the food safety hazards of pathogen growth and toxin formation.

- You must enter processing and other information on the monitoring records at the time it was observed to comply with 21 CFR 123.9(a)(4). However, your firm completes the records to monitor the cooking and post cooking critical control points listed in your hazard analysis for crawfish tail meat prior to the close of business each day.

In addition, the investigator documented numerous insanitary conditions that cause your crawfish tail meat to be adulterated within the meaning of Section 402(a)(4) of the Act. They are adulterated because they have been prepared, packed or held under conditions whereby they may become contaminated with filth.

- Employees working in direct contact with food and food-contact surfaces did not take necessary precautions to protect against cross contamination from unclean objects. For example:

  1. They contacted insanitary equipment and then handled various products without washing or sanitizing their hands;

  2. Their personal food items were stored directly above uncovered cooked product in the cooler;

  3. They used hand sanitizers that contained a concentration of iodine (less than 12 ppm) that was not adequate to sanitize their hands; and,

  4. They did not wear adequate hair restraints during operations.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating.

Please respond in writing within three (3) weeks from receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as copies of your HACCP plan or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations and the Good Manufacturing Practice regulations (21 CFR 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Your response should be directed to Mark W. Rivero, Compliance Officer, at the above address.

Sincerely,

Patricia K. Schafer

Patricia K. Schafer
Acting District Director
New Orleans District

Enclosure: Form FDA 483